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Under the Panerwork Reduction Act of 198  TRANSMITTAL FORM  (to be used for all correspondence after initial  Total Number of Pages in This Submission		U.S. Pate s are required to respond to a collect Application Number  Filling Date  First Named Inventor  Art Unit  Examiner Name  Attorney Docket Number	ont and Tration of info 10/694	r 27, 2003 nalla et al.
Fee Transmittal Form Fee Attached Amendment/Reply After Final Affidavits/declaration(s) Extension of Time Request Express Abandonment Request Information Disclosure Statement Certified Copy of Priority Document(s) Response to Missing Parts/ Incomplete Application Response to Missing Parts under 37 CFR 1.52 or 1.53	Rema * Copy	Drawing(s)  Licensing-related Papers  Petition  Petition to Convert to a  Provisional Application  Power of Attorney, Revocation  Change of Correspondence Add  Terminal Disclaimer  Request for Refund  CD, Number of CD(s)  rks  of postcard  Form1 449		After Allowance communication to Technology Center (TC)  Appeal Communication to Board of Appeals and Interferences Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)  Proprietary Information  Status Letter Other Enclosure(s) (please Identify below):
Firm or Individual name  Signature  Date  Wayne A. Keown, Ph.D.  Wayne A. Keown, Ph.D.  Value A. Keown, Ph.D.  Val	(Reg. No.	OF APPLICANT, ATTORI 33,923) CATE OF TRANSMISSIO		

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Kandimalla et al.

Serial No.:

10/694,207

Filed:

October 27, 2003

**Entitled:** 

Modulation of Immunostimulatory Activity of

Immunostimulatory Oligonucleotide Analogs by Positional

**Chemical Changes** 

Examiner:

NA

**Group Art Unit:** 

NA

**Attorney Docket No.:** 

**HYB-005US7 (1006/006)** 

Commissioner for Patents P. O. Box 1450 Alexandria, VA 22313-1450

#### INFORMATION DISCLOSURE STATEMENT

Sir:

Applicants and their attorney are aware of the following publications and information listed on the attached PTO Form 1449, and in accordance with 37 C.F.R. §1.97 hereby submit these publications for the Examiner's consideration.

Applicants state that the current application is a Divisional application claiming priority to U.S. Patent Application Serial No. 09/965,116, filed September 26, 2001. Applicants also state that the references listed on the attached PTO Form 1449 were previously cited in the parent case and therefore copies of the references are not enclosed herewith.

This submission does not represent that a search has been made and does not constitute an admission that the listed documents are material to patentability or that the listed documents are prior art. If it should be determined that any of the listed documents constitute "prior art" under United States law, Applicants reserve the right to present to the Office relevant facts and law regarding the appropriate status of such documents.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits and is therefore submitted as both timely and proper. Therefore, no fees are believed to be due.

Respectfully submitted,

Date: 2/5/04

Wayne A. Keown Reg. No. 33,923

Keown & Associates 500 West Cummings Park Suite 1200 Woburn, MA 01801 781-938-1805 (Telephone) 781-938-4777 (Facsimile) O P E Subt. Form PTO-1449
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# INFORMATION DISCLOSURE IN AN APPLICATION

Docket Number

**Application Number** 

HYB-005US7

10/694,207

Applicant

(Use several sheets if necessary)

Kandimalla et al.

Sheet 1 OF 2

Filing Date 10/27/03 Group Art Unit

O3 NA

U.S. Patent Documents						
EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	5,149,798	09/22/92	Agrawal et al.	536	27	

		For	eign Patent Docu	ments			
EXAMINER	DOCUMENT	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
INITIAL	NUMBER		00011111			YES	NO
	WO99/62923		PCT				

	Other Documents (Including Author, Title, Date Pertinent Pages, Etc.)
C1.	Knorana et al. (1972) "Studies on Polynucleotides," J. Molec. Biol. 72:209
C2.	Reese (1978) "The Chemical Synthesis of Oligo- and Poly-Nucleotides By The Phosporotriester Approach," Tetrahedron 34:3143-3179
C3.	Beaucage et al. (1981) "Deoxynucleoside Phosphoramidites – A New Class of Key Intermediates for Deoxypolynucleotide Synthesis," Tetrahedron Lett. 22:1859-1862
C4.	Connolly et al. (1984) "Synthesis and Characterization of an Octanucleotide Containing the EcoRl Recognition Sequence With A Phosphorothicate Group At The Cleavage Site." Biochemistry 23:3443
C5.	Agrawal et al. (1987) "Oligodeoxynucleotise Methylphosphonates: Synthesis and Enzymic Degradation,"  Tetrahedron Lett. 28(31):3539-3542
C6.	Jager et al. (1988) Oligonucleotide N-Alkylphosphoroamidates: Synthesis and Binding to Polynucleotides,"  Biochemistry 27:7237
C7.	Agrawal et al. (1988) "Oligodeoxynucleoside Phosphoroamidates and Phosporothioates As Inhibitors of Human Immunodeficiency Virus, <i>Proc. Natl. Acad. Sci. USA</i> 85:7079-7083
C8.	Zon et al. (1991) "Phosphorothicate Oligorculeotides" Oligonucleotides and Analogues: A Practical Approach pp. 87-108
C9.	Kuramoto et al. (1992) "Oligonucleotide Sequences Required For Natural Killer Cell Activation," <i>Jpn. J. Cancer Res.</i> 83:1128-1131
C10.	CRC Press, Boca Raton, Florida
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C12.	Pisetsky et al. (1994)"Stimulation of Murine Lymphocyte Proliferation By A Phosphorothicate Oligonucleotide With Antisense Activity For Herpes Simplex Virus," 54 Life Sci. 101
C13.	Yamamoto et al. (1994) "Lipofection of Synthetic Oligodeoxyribonucleotide Having a Palindromic Sequence of
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C15.	Krieg et al. (1995) "CpG Motifs in Bacterial DNA Trigger Direct B-Cell Activation," Nature 371:546-549
C16.	Klinman et al. (1996) "CpG Motifs Present in Bacterial DNA Rapidly Induce Lymphocytes to Secrete Interleukin 6, Interleukin 12, and Interleron γ," 93 <i>Proc. Natl. Acad. Sci. USA</i> 2879
C17.	Llang et al. (1996) "Activation of Human B Cells By Phosphorothioate Oligodeoxynucleotides," J. Clin. Invest. 98:1119-1129
C18.	Zhao et al. (1996) "Effect of Different Chemically Modified Oligodeoxynucleotides on Immune Stimulation," <i>Biochem. Pharm.</i> 51:173-182
C19.	Chu et al. (1997) "CpG Oligodeoxynucleotides Act As Adjuvants That Switch On T Helper 1 (Th1) Immunity," 186 J. Exp. Med. 1623

EXAMINER	DATE CONSIDERED			
EXAMINER: Initial if citation is considered, whether or not citati	on is in conformance with MPEP § 609: Draw Line through citation			

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Subt. Form PTO-1449	Docket Number	Application Number
INFORMATION DISCLOSURE IN AN APPLICATION	HYB-005US7	10/694,207
rea 1 9 cpus 34	. Appli	cant
(Use several sheets if necessary)	Kandimalla et	al.
We will be a second of the sec	Filing Date	Group Art Unit
Sheet 2 OF 2	10/27/03	NA

C20	Abstract, pp. 40
C21	Mediated Shock," 27 Eur. J. Immunol. 1671
C22	Oligonucleotides in Mice," 7 Antisense Nucleic Acid Drug. Dev. 495
C23	Hesponses Against Hepatitis B Surface Antigen with Intranasal Administration to Mice," J. Immunol, 161:4463-4466
C24	Moldoveanu et al. (1998) "CpG DNA, A Novel Immune Enhancer for Systemic and Mucosal Immunization With Influenza Virus," Vaccine 16:1216-1224
C25	Sparwasser et al. (1998) "Bacterial DNA and Immunostimulatory CpG Oligonucleotides Trigger Maturation and ACtivation of Murine Dendritic Celts," 28 Eur. J. Immunol. 2045
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C27	Theo et al. (1900) "Site of Chemical Medifications in Co.C. Containing Pheenhousthicate Office described
C28	Agrawal et al. (2000) "Antisense Therapeutics: Is it As Simple As Complementary Base Recognition," 6 Mol. Med. Today 72
C29	Modulated by Modification of a Single Deoxynucleoside," <i>Bloorg, &amp; Med, Chem, Lett.</i> 10:1051-1054
c3	<pre>Q Agrawal et al., "Antisense therapeutics", Curr. Opin.Chem. Biol., 2:519-528, 1998.</pre>
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C3	3 Yu et al., "Accessible 5'-End of CpG-Containing", Biographic & Medicinal Chemistry Lett., 10:2585-2588, 2000
C3	4 Kandimalla et al., "Effect of Chemical Modifications", Bioorganic & Medicinal Chemistry, 9:807-813, 2001.
C3	International Search Report (PCT APP. No. PCT/USO1/30137).
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